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SEP 14 2011

510(k) Summary

AS REQUIRED BY 21 CFR 807.92(c)

The Assigned 510(k) number is k111322

Date of Summary: September 11th, 2011

Common Name: Drugs of Abuse Screening Tests

Classification Name: Immunoassay for the detection of drugs of abuse

Trade/Proprietary Name:

Chemtron Biotech, Inc.'s Chemtrue® Single / Multi-Panel Drug Screen Dip Card / Cassette Tests, contain 1 to 6 of the following DOA test(s) in each device:

1. Benzodiazepines (BZO) test strip
2. Barbiturates (BAR) test strip
3. Ecstasy (MDMA/XTC) test strip
4. Methadone (MTD) test strip
5. Opiates /Morphine (OPI/MOR/MOP) cut-off: 2000ng/mL test strip
6. Oxycodone (OXY) test strip

Owner:

Ellen Liu
President, Chemtron Biotech, Inc.
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Contact Person:

Jane Zhang, Director of QA/RA
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Substantial Equivalency:

The Chemtrue® Single/Multi-Panel Drug Screen Test is substantially equivalent to other tests currently on the market.

Test Analyte	Predicate Device Name	Predicate Device 510(k) #
Benzodiazepines	ACON (Alere) One Step Drug Screen Test Card	K061718
Barbiturates	ACON (Alere) One Step Drug Screen Test Card	K061718
Ecstasy (MDMA)	ACON (Alere) One Step Drug Screen Test Card	K061718
Methadone	ACON (Alere) One Step Drug Screen Test Card	K061718
Opiates (Morphine)2000	ACON (Alere) One Step Drug Screen Test Card	K061718
Oxycodone	ACON (Alere) One Step Drug Screen Test Card	K061718

The predicate kit package insert is enclosed in ATTACHMENT A of this submission.

Proposed Labeling or Promotional Material for the Device:

A description of the device can be found in the attached proposed labeling, including an explanation of how the device functions, technical principle and concepts that form the basis for the device, as well as the physical and performance characteristics of the device, such as the device design, materials used and physical properties. In accordance with FDA labeling requirements (21 CFR 809.10), enclosed are the draft copies of product labeling including copies of the technical product inserts. See ATTACHMENT B, C and D.

Intended Use

The Chemtrue® test device is intended for the qualitative detection of drugs of abuse, for *in vitro* diagnostic use and for prescription use ONLY.

The test provides only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

Technological Characteristics and Scientific Principles

The Drugs of Abuse (DOA) Screen Panels are one-step lateral flow immunoassays in which chemically modified drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs that may be present in urine. The test device consists of up to six test strips placed into separate panels of a plastic holder. On each test strip, a drug-protein

conjugate is striped on the test band of the membrane - known as the test region (**T**) and the anti-drug antibody-colloidal gold conjugate pads are placed at the forward end of the membrane. In the absence of drugs in the urine, the solution of the colored antibody-colloidal gold conjugates moves along with the sample solution by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines. Therefore, the formation of the visible precipitant in the test band occurs when the test urine is negative for the drug. If any of the subject drugs of abuse is present in the urine, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. When a sufficient amount of drug is present in the urine, the drug will saturate the limited antibody binding sites and the colored antibody -colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result.

A control band with a different antigen/antibody reaction is added to the membrane strip at the control region (**C**) to indicate that the test has performed properly. This control line is manufactured as a built-in internal control of the test device and should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test should be discarded. The presence of this colored band in the control region also serves: 1) as verification that adequate specimen volume is added, or no flow, due to insufficient urine volume, 2) to indicate that the test device is properly functioning, and 3) as an internal quality control of the system.

Summary of Device Similarities and Differences

Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card tests are similar to other FDA-cleared devices for the qualitative detection of drugs of abuse: Benzodiazepines, Barbiturates, Ecstasy (MDMA), Opiates (Morphine) 2000, Methadone and Oxycodone test from other manufacturers such as ACON (Alere), Alfa Scientific Designs, Inc. All of these products are based on the same technological characteristics, scientific principle and similar procedures. The similarities and differences among these tests are summarized as follows:

SIMILARITIES		
Item	**Chemtrue® Device**	**Predicate Kit**
Intended Use/Indications for use	Qualitative detection of drugs-of- abuse in urine for Prescription, *In Vitro* Diagnostic Use Only	Same
Specimen	Urine	Same
Technological Characteristics and Principle	One-Step lateral flow competitive Immunoassay	Same

Device Design/ Performance	**Positive result**	1 colored line	Same
	Negative result	2 colored lines	Same
	Detection reagent	Colloidal gold	Same
	Accuracy Assessment	Confirm with GC/MS reference method	Same
Cut-off		Benzodiazepines 300 ng/mL Barbiturates 300 ng/mL Ecstasy (MDMA) 500 ng/mL Methadone 300 ng/mL Opiates(Morphine) 2000 ng/mL Oxycodone 100 ng/mL	Same Same Same Same Same Same
Safety and Precaution		All urine specimens should be considered potentially hazardous and handled in the same manner as infectious agent.	Same
Read time		5 minutes	Same
Storage		2 – 30°C (36 – 86°F)	Same

DIFFERENCES		
Item	Chemtrue® **Device**	**Predicate Kit**
Pre-treatment for urine specimen	Does not require pre-treatment for urine specimen. It is ease of use.	Urine specimen needs to be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
Time To Read Result	Do not read after 8 minutes.	Results remain stable for up to 4 hours after test initiation.

DISCUSSION AND CONCLUSION:

Based on the technological characteristics/assay principle, features of the device designs, test specimen matrix, test method and performance characterizations, as the set forth above, it can be concluded that Chemtrue® Single/ Multi-Panel Drug Screen tests are substantially equivalent to the predicate kit ACON's (INNOVACON/Alere) One Step Single and Multi Drug Screen test card product which is currently distributed commercially.

The Chemtrue® Drug Screen Tests do not require pre-treatment for urine specimen, thereby making it much simpler and convenient for the intended user. With regarding to the difference of Time to read result, since the device labeling clearly indicates the required "Read Time", it does not impact the result interpretation by the intended user.

Performance Data:

Chemtron Biotech, Inc. has reviewed the requirements of Section 514 of the Act, which states that to date no performance standards has been established for drug screen test systems by the FDA.

However, the studies listed in the notification are conducted according to "The Draft Guidance for Industry and FDA Staff" - " Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests, issued on: December 2, 2003", including the design of draft labeling and package inserts.

Chemtrue® Single / Multi-Panel Drug Screen Cassette and Dip Card tests are one-step, lateral flow, colloidal gold based immunoassays for the rapid, qualitative detection of Benzodiazepines, Barbiturates, Ecstasy (MDMA), Opiates (Morphine) 2000, Methadone and Oxycodone in human urine. They are intended for Professional Use and Prescription Use ONLY.

For BAR or BZO test, it may yield preliminary positive results when BAR or BZO is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate and benzodiazepine in urine. The Chemtrue® Single / Multi-Pane drugs of abuse urine test device shows the drug was or was not present at the cutoff level.

The assay provides a preliminary test result. A more specific alternate chemical method must be used to obtain a confirmed assay result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory result. Clinical and professional judgment must be applied to any drugs of abuse test result, particularly when preliminary positive results are obtained.

Chemtrue® Single /Multi-Panel Drug Screening Tests *vs* GC/MS Reference Method

Samples with drug concentration above the cut-off level were considered presumptive positive and concentration below the cut-off were considered negative.

Table 1. The data are a summary from a method comparison (Accuracy) study of Chemtrue® Drug Screen Dip Card Test results versus GC/MS values of the clinical specimens

Test	Positive Agreement	Negative Agreement	Overall Agreement
BZO	116/118 = 98.3%	84/85 = 98.8%	200/203 = 98.5%
BAR	103/105= 98.1%	84/85= 98.8%	187/190= 98.4%
MDMA	40/41= 97.6%	59/60 = 98.3%	99/101 = 98%

MTD	44/44 = 100%	59/60 = 98.3 %	103/104 = 99%
OPI(MOR)2000	41/41= 100%	65/65= 100%	106/106= 100%
OXY	47/47 = 100%	58/59= 98.3%	105/106= 99.1%

Table 2. The data are a summary of a method comparison (Accuracy) study of Chemtrue® Drug Screen Cassette Test results versus the GC/MS values of the clinical specimens

Test	Positive Agreement	Negative Agreement	Overall Agreement
BZO	116/118 = 98.3%	84/85= 98.8%	200/203 = 98.5%
BAR	103/105= 98.1%	84/85= 98.8%	187/190= 98.4%
MDMA	40/41= 97.6%	59/60 = 98.3%	99/101 = 98%
MTD	44/44 = 100%	59/60 = 98.3 %	103/104 = 99%
OPI(MOR)2000	41/41= 100%	65/65= 100%	106/106= 100%
OXY	47/47 = 100%	58/59= 98.3%	105/106= 99.1%

Conclusion:

The product performance characteristics of were evaluated with the GC/MS confirmed values in a blind-labeled clinical specimen correlation study. The results of these studies demonstrate Chemtrue® Single/ Multi-Panel Drug Screen Test to be substantially in agreement with the GC/MS assigned values.

Additionally, the Chemtrue® Single/ Multi-Panel Drug Screen tests were shown to be equivalent, when compared to the data in the package insert of the predicate kit ACON (INNOVACON/Alere) One Step Drug Screen test card. These results demonstrated that Chemtrue® Single/ Multi-panel Drug Screen cassette and Dip Card are safe and effective in detecting Benzodiazepines, Barbiturates, Ecstasy (MDMA), Methadone, Opiates (Morphine) 2000 and Oxycodone in human urine.

Other non-clinical performance data, such as cutoff characteristics, precision (Reproducibility), specificity (Cross-reactivity and interference) and stability studies are summarized in the Section labeled "Performance Characteristics" and the raw data are enclosed in ATTACHMENT E and ATTACHMENT H of this submission.

510(k) Summary was revised By: Jane Zhang on September 11th, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 1 6 2011

Chemtron Biotech, Inc.
c/o Jane Zhang
8370 Juniper Creek Lane Suite 1-2
San Diego, CA 92126

Re: k111322
Trade/Device Name: Chemtrue Single/Multi-Panel Drug Screen Cassette and Dip Card Tests
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine test system
Regulatory Class: Class II
Product Code: JXM, DIS, DJC, DJR, DJG
Dated: August 18, 2011
Received: August 19, 2011

Dear Ms Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k111322

Device Name: Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests

Indications for Use:

The Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of up to six of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and the calibrators used for these drugs are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration
Benzodiazepines	BZO	Oxazepam	300 ng/mL
Barbiturates	BAR	Secobarbital/Pentobarbital	300 ng/mL
Ecstasy	MDMA/XTC	d,l-Methylenedioxymethamphetamine	500 ng/mL
Methadone	MTD	Methadone	300 ng/mL
Opiates	OPI/MOR	Morphine	2000 ng/mL
Oxycodone	OXY	Oxycodone	100 ng/mL

The Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are intended for the qualitative detection of drugs of abuse for *in vitro* diagnostic and prescription use ONLY. They are not intended for point-of-care settings or over the counter use. These assays provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k111322